

## EXHIBIT J



# Comparative strengths and structural properties of the upper and lower cervical spine in flexion and extension

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## Abstract

The purpose of this study is to test the hypothesis that the upper cervical spine is weaker than the lower cervical spine in pure flexion and extension bending, which may explain the propensity for upper cervical spine injuries in airbag deployments. An additional objective is to evaluate the relative strength and flexibility of the upper and lower cervical spine in an effort to better understand injury mechanisms, and to provide quantitative data on bending responses and failure modes. Pure moment flexibility and failure testing was conducted on 52 female spinal segments in a pure-moment test frame. The average moment at failure for the O-C2 segments was  $23.7 \pm 3.4$  Nm for flexion and  $43.3 \pm 9.3$  Nm for extension. The ligamentous upper cervical spine was significantly stronger in extension than in flexion ( $p = 0.001$ ). The upper cervical spine was significantly stronger than the lower cervical spine in extension. The relatively high strength of the upper cervical spine in tension and in extension is paradoxical given the large number of upper cervical spine injuries in out-of-position airbag deployments. This discrepancy is most likely due to load sharing by the active musculature. © 2002 Elsevier Science Ltd. All rights reserved.

**Keywords:** Cervical spine; Bending; Strength; Airbag; Odontoid

## 1. Introduction

Restraint devices for motor vehicle occupants have become increasingly more advanced and complex over the past decade. However, as injury prevention technologies have progressed, the parameters used to assess injury risk in new motor vehicles have remained relatively unchanged. In order to keep pace with new technologies, and to advance the state of the art in injury prevention, the United States National Highway Traffic Safety Administration (NHTSA) is proposing new injury standards for the 30 mph barrier impact test (FMVSS 208). These include new neck injury criteria that will utilize both axial and bending loads in the formulation of injury reference values for Anthropomorphic Test Devices (ATDs).

One of the objectives of the new neck injury standard is to prevent airbag-related injuries, particularly to the upper cervical spine (O-C2). The US National Center

for Statistics and Analysis (NCSA) has been conducting Special Crash Investigations (SCIs) since 1991 on all airbag injuries in low to moderate severity crashes [<http://www.nhtsa.dot.gov/people/ncsa/sci3.html>]. Most of these injuries occur when the occupant is out-of-position and close to the airbag module. The data from the SCIs show that 78% of the cervical spine injuries in adults are occurring between the occiput and C2. This is considerably higher than upper cervical spine injury rates in the general population (Hadley et al., 1986; Levine and Edwards, 1986; Myers and Winkelstein, 1995). The specific mechanisms by which these injuries occur are still unclear. It is generally assumed that neck injury in airbag deployments is caused by tension and extension secondary to direct loading of the head and mandible (Blacksin, 1993; Maxeiner and Hahn, 1997). Studies using ATDs have demonstrated large tensile forces and extension moments when the dummies are close to deploying airbags (Pintar et al., 1999; Tylko and Dalmotas, 2000).

The new neck injury criteria employ a linear combination of normalized neck axial force ( $F_z$ ) and neck moment at the occipital condyles ( $M_y$ ). The

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formulation is  $N_{ij} = F_{NZ} + M_{NY}$ , where  $F_{NZ} = F_Z/F_{ZCRIT}$  and  $M_{NY} = M_Y/M_{YCRIT}$ . The axial force and the moment are measured at the same time point, and the critical values are the intercepts for axial load (tension or compression) and moment (flexion or extension). The  $N_{ij}$  cannot exceed 1.0 at any point in time during a crash test. The most important parameters in this criterion are the critical values for tension and extension. There have been a number of studies on the strength of the neck in tension (Cheng et al., 1982; Sances et al., 1981; Shea et al., 1992; Van Ed et al., 2000; Yoganandan et al., 1996); however, there are no studies on the strength of the ligamentous cervical spine in bending. As a result, the proposed bending tolerance values for the human upper cervical spine are highly inferential (Mertz and Patrick, 1971; Mertz and Prasad, 2000). The lack of data on the strength of the cervical spine in pure bending has been an impediment to the development of new neck injury standards for crash testing.

The purpose of this study is to test the hypothesis that the upper cervical spine is weaker than the lower cervical spine in flexion/extension bending, which may explain the propensity for upper cervical spine injuries in airbag deployments. The hypothesis was tested by using pure bending moments to produce injuries in human cadaver spinal segments. A secondary goal of this study is to provide previously unavailable biomechanical data on the bending responses and the bending strength of the human cervical spine. These data will assist in the development of injury criteria for combined tension and bending of the neck. They will also assist in the development of new physical and computational models of the neck.

## 2. Methods

Testing was performed on 52 unembalmed spinal segments from 16 cervical spines. Donor age ranged from 33 to 66 years ( $50.8 \pm 8.8$ , mean  $\pm$  standard deviation). To minimize variance, only female cervical spines were used (Nightingale et al., 1997). The muscular tissues were removed while keeping all the ligamentous structures intact (with the exception of the ligamentum nuchae). All specimen handling was performed in compliance with CDC guidelines (Cavanaugh and King, 1990). The cervical spines were sectioned into 4 groups: O-C2, C3-C4, C5-C6, and C7-T1. The lower cervical motion segments were cleaned and cast into aluminum cups with fiber-reinforced polyester resin. The cephalad end of the upper cervical spine specimens was secured using halo fixation. The mandible and maxilla were removed in order to allow unimpeded range of motion. Upper cervical specimens (O-C2) were inverted and

mounted in the test frame using halo fixation of the head and casting of the C2 vertebra.

Bending tests were performed in a pure-moment test frame (Camacho et al., 1997; Winkelstein et al., 2000). The moments were generated using a pair of free-floating pneumatic pistons to apply a force-couple. Angular displacement data was acquired using a Kodak Ektapro EM-2 digital camera. After the specimen was mounted in the test frame, a counterweight was applied to the upper casting assembly (Fig. 1). The counterweight counterbalances the mass of the assembly, and applies 0.5 N of tension on the vertebra. The purpose of the 0.5 N tensile load was to establish a repeatable initial position near the middle of the neutral zone. This was necessary because spine segments are unstable under the action of gravity (Panjabi et al., 1998). The specimen was imaged in the initial position and the load cell values were zeroed. This image served as the reference position for the flexibility tests and for the failure tests.

Prior to flexibility testing, the specimens were preconditioned with 30 cycles of  $\pm 1.5$  Nm of moment. Then each specimen was loaded with pure flexion and extension moments in 0.5 Nm increments. Thirty seconds of creep was allowed prior to data acquisition, and the load was released between load steps. The peak-applied moment was approximately 3.5 Nm. A 6-axis load cell (GSE model 6607-00) at the base of the specimen was used to measure the applied moment and to ensure that the moment remained pure. The load application, test duration, data acquisition, and load release were all controlled by PC based software (National Instruments).

For failure testing, the tension mass was removed, and the specimens were failed in either flexion or

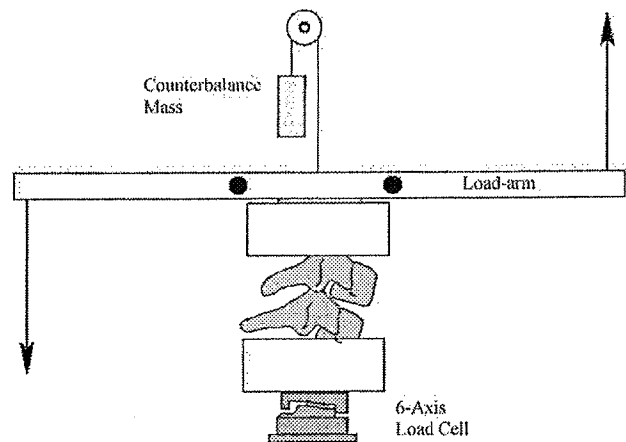


Fig. 1. A schematic of the apparatus used to apply pure flexion and extension moments. Angular displacements were measured by optical tracking of the spherical markers on the couple-arm. The O-C2 spinal units were inverted and were attached to the load cell via halo fixation. The counterbalance mass was used to minimize the loads imposed by the load-arm and casting cup. A 6-axis load cell was used to measure the applied moment and to ensure that the load remained pure.

extension. The loading rates were dependent on the flexibility of the specimen, and were near 90 N/m/s. These tests were imaged at 125 frames/s for 3.2 s. Failures were defined as a decrease in the measured moment with increasing rotation, and they were verified by examination of the high-speed images. Specimen dissection was performed to document injuries.

All the image data was uploaded to a Silicon Graphics workstation and digitized using a modified version of the xv shareware (v3.10a, John Bradley). In order to increase spatial resolution, the software was modified to use a weighted average based on pixel gray scale levels to find the center of the optical markers. The accuracy of the angular displacement measurements was  $0.06^\circ$  for the field-of-view used in this study. Angular displacements for each image were determined with respect to the reference image.

In order to formulate a functional relationship between moment and angle, the data for each bending test was fit with a nonlinear function of the form:

$$\theta = A \ln(BM + 1), \quad (1)$$

where  $\theta$  is the angle,  $M$  is the applied moment, and  $A$  and  $B$  are model constants. This function has been widely used to model the nonlinear behavior of soft tissues (Fung, 1972; Simon et al., 1984). Because the independent variable (moment) was not the same for all specimens (due to frictional losses in the system), it was not possible to average the responses for each spinal segment prior to fitting. Instead, individual flexibility functions were determined for every specimen tested. The functions were grouped by spinal segment, and the computed values within each group were averaged at 0.5 N/m intervals, and fit for a second time.

Analysis of variance and Tukey tests were used to evaluate differences in the range of motion (ROM) between spinal segments. Nonparametric ANOVA (Kruskal–Wallis) and multiple comparisons testing (Dunn) were used to determine if there were any differences in strength between the spinal segments. Nonparametric tests (Mann–Whitney) were used to determine if there were any differences in flexion and extension tolerance for each segment tested. All statistical analysis was done at a significance level of 0.05.

### 3. Results

The correlation coefficients for the individual flexibility functions were all  $>0.98$ , and the correlation coefficients for the averaged flexibility functions were all  $>0.99$ . The coefficients for the functions describing the average response of all the spinal segments are given in Table 1. Plots of the averaged flexibility functions for all the segments are shown in Fig. 2.

The tolerance data for all the motion segments are summarized in Tables 2 and 3. Two C6–C7, and one C4–C5 motion segments are included in Table 3. These segments came from cervical spines that had anomalies or fusions at one or more of the desired levels; therefore, alternative levels were tested.

For applied moments of  $-3.5$  to  $+3.5$  N/m, the ranges of motion for the C7–T1, C5–C6, C3–C4, O–C2 segments were  $13.8 \pm 2.8^\circ$ ,  $22.8 \pm 2.3^\circ$ ,  $20.8 \pm 3.0^\circ$ , and  $58.4 \pm 10.7^\circ$ , respectively. These were significantly different (Table 4).

The upper cervical spine was significantly stronger in extension than in flexion (Mann–Whitney,  $p = 0.001$ ). The average moment at ultimate failure for the O–C2 segments was  $23.7 \pm 3.4$  N/m for flexion and  $43.3 \pm 9.3$  N/m for extension (Fig. 3). The C3–C4 motion segment was also stronger in extension than in flexion ( $p = 0.02$ ). There were no significant differences between flexion and extension strengths for the C5–C6, and C7–T1 segments.

Kruskal–Wallis testing demonstrated significant differences in the flexion strengths between spinal segments. Follow-up multiple comparisons testing (Dunn) showed that in flexion, both the O–C2 and the C7–T1 segments were significantly stronger than C3–C4. All other differences in flexion strength were not statistically significant (Table 4).

Kruskal–Wallis testing also demonstrated significant differences in the extension strengths between spinal segments. Dunn testing showed that O–C2 had greater extension strength than all the lower cervical spine motion segments. There were no significant differences among the lower cervical spine motion segments in extension (Table 4).

The injuries produced in the upper cervical spine included Type III dens fractures, atlanto-occipital sprains and disruptions, and hangman's fractures (Table 5). However, many of the tests either did not produce injury, or produced failures of the specimen fixation. For the fixation failures and the nonfailures, the maximum moment and angle recorded during the test are reported in the Table 2. Despite the inclusion of these data in the statistical analysis, our results show differences in strength (flexion vs. extension). Had these specimens actually failed, they would have done so at a

Table 1  
Coefficients for the logarithmic model

	Flexion		Extension	
	$A$ (deg)	$B$ (1/Nm)	$A$ (deg)	$B$ (1/Nm)
O–C2	11.57	3.76	–4.08	–231.43
C3–4	4.59	3.72	–4.66	–1.64
C5–6	3.73	10.65	–4.76	–1.70
C7–1	2.48	4.90	–4.85	–0.81

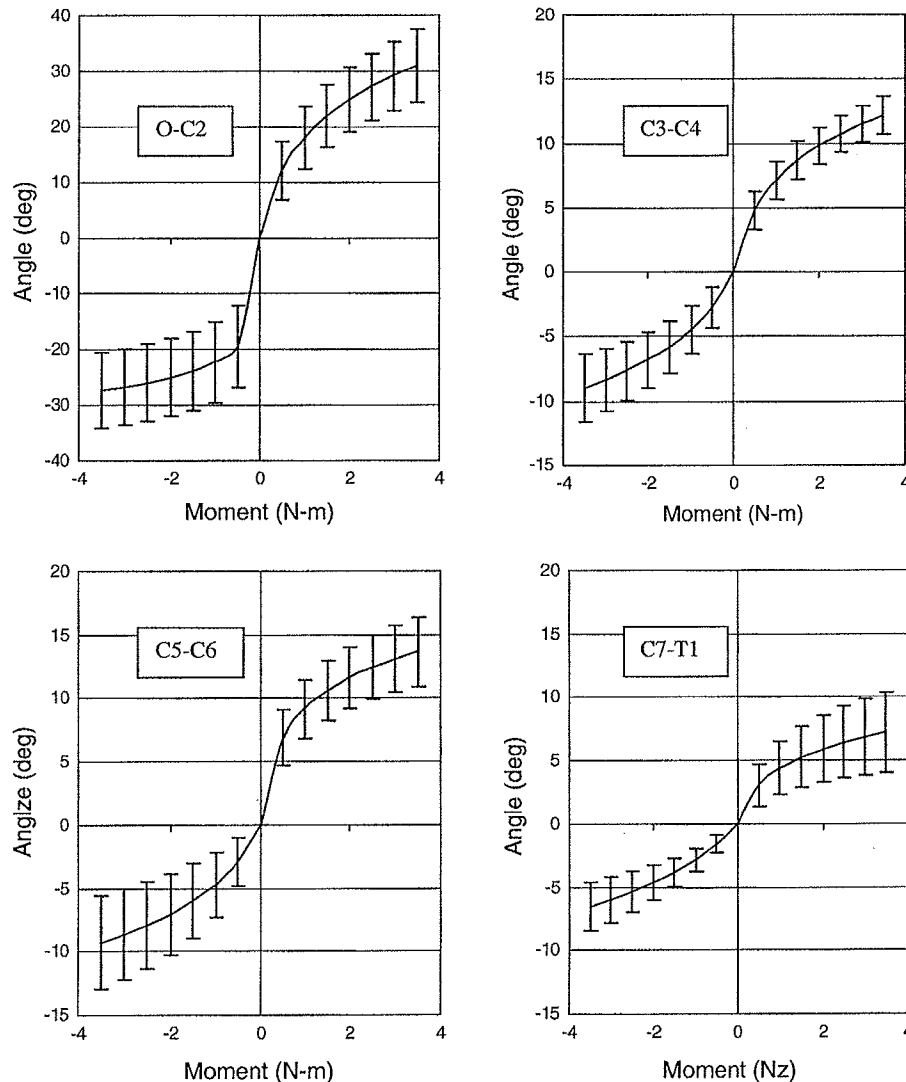


Fig. 2. Plots of the averaged flexibility models for all the tested spinal segments. The error bars are  $\pm 1$  standard deviation. The coefficients for the logarithmic functions are given in Table 1.

higher load, and would have likely increased our  $p$  values.

The types of injuries produced in the lower cervical spine were dislocations (complete disruption of all the ligamentous structures between the bodies, including the disc), posterior element fractures, and body fractures. Although there were no fixation failures in the lower cervical spine motion segments, many of the fractures passed through the holes made for the fixation wires.

The average angle at injury for the upper cervical spine in flexion was  $56.2 \pm 2.3^\circ$ . The average angle at injury in extension was  $50.2 \pm 11.4^\circ$ . For the lower cervical spine, the average angle at injury in flexion was  $19.3 \pm 5.4^\circ$ . The average angle at injury in extension was  $20.5 \pm 7.2^\circ$ .

#### 4. Discussion

The results for the flexibility tests are in good agreement with previously published studies, despite the fact that previous studies used mixed genders (Goel et al., 1988; Panjabi et al., 1991, 1994; Voo et al., 1998) (Table 6). The flexibility results are based on a larger sample size than in prior studies and, with the exception of the work by Voo et al., 1998, the moments applied are of considerably larger magnitude ( $\pm 3.5$  N m). Most previous studies have focused on the small-moment responses with the goal of quantifying clinical stability and neutral zone in normal, pathological, and instrumented segments. Therefore, the flexibility functions in this manuscript provide more complete biomechanical data on which to base the motion segment properties of



Table 2  
Failure data for upper cervical spinal segments

Test ID	Flexion		Test ID	Extension	
	Nm	Angle		Nm	Angle
b03fo2*	68.62	56.99	b02fo2	45.19	na
b07fo2	23.77	58.50	b04fo2	34.46	39.74
b09fo2	27.15	55.16	b05fo2	30.03	35.92
b10fo2*	45.91	62.25	b06fo2**	26.64	21.35
b14fo2	24.73	58.49	b11fo2*	65.52	54.36
b15fo2	19.00	52.75	b12fo2	36.86	59.18
			b13fo2	52.60	na
			b16fo2	42.76	na
			b17fo2	57.46	56.53
			b18fo2	47.05	59.63
Mean	23.66	56.23	Mean	43.30	50.20
SD	3.42	2.80	SD	9.26	11.43

Footnoted values were not included in the statistical analysis because:  
\*there was contact between the casting cup and either the skull-base or maxilla, which created an alternative load path for moments, \*\*the specimen had fused occipital condyles.

Table 3  
Failure data for lower cervical spine motion segments

Test ID	Flexion		Test ID	Extension	
	Nm	Angle		Nm	Angle
b02f45	11.90	na	b02f67	19.88	na
b03f56	17.20	18.20	b03f34	13.50	22.70
b04f34	9.00	16.50	b03f71	16.94	14.30
b04f71	21.36	21.35	b04f56	12.31	17.13
b05f56	15.95	29.14	b05f34	15.15	14.88
b06f34	14.64	17.06	b05f71	26.32	24.52
b06f71	21.74	14.47	b07f34	14.96	19.83
b07f56	18.91	29.07	b07f71	25.85	14.64
b10f56*	25.62	na	b10f34	28.23	18.68
b11f45	11.56	19.78	b10f71	41.51	15.24
b11f67	23.54	24.43	b12f56	12.28	12.46
b12f34	12.70	13.83	b13f56	23.43	16.20
b12f71	18.54	8.73	b14f34	25.33	na
b13f34	11.73	17.93	b14f71	28.98	26.18
b14f56	13.65	19.08	b15f34	19.33	38.90
b15f56	12.70	19.34	b15f71	19.17	30.59
b16f34	18.59	na	b16f56	17.56	20.54
b16f71	34.06	20.97			
Ave	17.41	19.33	Ave	21.22	20.45
SD	6.22	5.39	SD	7.61	7.19

The first four characters of the Test ID are the specimen ID. The last two digits of the Test ID are the vertebral level tested. The angle data for some specimens is not available due to yielding of the fixation.

\*Not included in the statistical analysis because of contact between the casting cups.

future computational and physical models of the ligamentous cervical spine.

There are no published tolerance values for cervical spine motion segments subjected to pure bending. The values in this study are lower bounds for catastrophic

Table 4  
Results of the Tukey and Dunn multiple comparisons testing

	O-C2	C3-4	C5-6	C7-1
Flexion Strength				
O-C2		O	-	-
C3-4	O		-	O
C5-6	-	-		-
C7-1	-	O	-	
Extension Strength				
O-C2		O	O	O
C3-4	O		-	-
C5-6	O	-		-
C7-1	O	-	-	
Range of Motion				
O-C2		O	O	O
C3-4	O		-	-
C5-6	O	-		O
C7-1	O	-	O	

An O means there was a statistically significant difference ( $p < 0.05$ ).

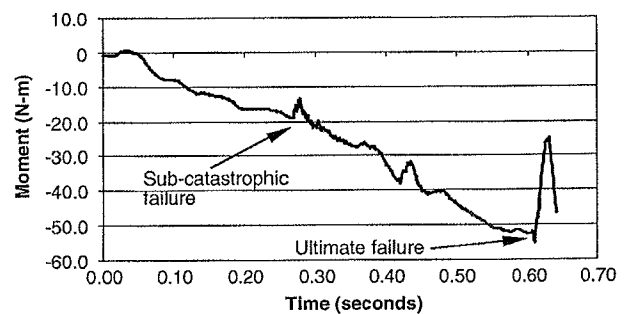


Fig. 3. Moment history for an extension failure test (b13fo2). The failure occurs at a time of 0.62s, and at a moment of 52.6 N.m.

injury in females because one of the upper cervical spine specimens did not fail, and others sustained fixation failures. It should also be noted that sub-catastrophic injuries often occurred at lower loads. Achieving adequate fixation was the greatest challenge in performing this study. Unlike compression testing, where loads can be easily distributed over large contact areas, bending tests produce large tensile stresses that must be reacted by fixation wires and screws. New wiring techniques were developed, including crossed wires through the vertebral bodies and intraforaminal loops around the pedicles. Unfortunately, these wires create stress concentrations in the bone. Consequently, any osseous injuries that propagate through the fixation points occur at loads below the real tolerance of the motion segment.

Table 5  
Injuries for upper cervical spinal segments

Specimen	Age	Segment	Mode	Injury
B02f	66	O-C2	Extension	Type III dens fracture
B04f	46	O-C2	Extension	Hangman's fracture. C2 inferior endplate fracture
B05f	42	O-C2	Extension	Hangman's fracture. The C2 anterior fixation wires pulled through the endplate.
B06f	49	O-C2	Extension	Bilateral condylar fractures (the condyles were fused)
B11f	45	O-C2	Extension	C2 inferior endplate fracture and bilateral C2 lamina and spinous process fracture.
B12f	58	O-C2	Extension	Yielding of the fixation wires
B13f	52	O-C2	Extension	Halo fixation failed
B16f	41	O-C2	Extension	Fixation pulled through the C2 endplate
B17f	46	O-C2	Extension	No injury
B18f	56	O-C2	Extension	Fixation wires pulled out
B03f	51	O-C2	Flexion	Posterior atlanto-occipital ligament sprain
B07f	52	O-C2	Flexion	Halo fixation failed
B09f	66	O-C2	Flexion	PLL, tectorial membrane, and R alar ligament were torn
B10f	33	O-C2	Flexion	Sprain of the posterior O-A lig and the posterior capsules
B14f	56	O-C2	Flexion	Type III dens fracture
B15f	53	O-C2	Flexion	Type III dens fracture

Table 6  
Comparison of the flexibility functions with the literature

Study	Level	Moment (N·m)	Flexion (deg)	Extension (deg)	ROM* (deg)
Panjabi et al., 1994	C45,C56	1.5	8.3	−7.2	15.5
Goel et al., 1988	C34	0.3	<b>10.6</b>	<b>−6.0</b>	<b>16.6</b>
			3.5	−2.9	6.4
	C56	0.3	<b>3.4</b>	<b>−1.9</b>	<b>5.3</b>
			2.6	−2.6	5.2
Voo et al., 1998	C71	0.3	<b>5.4</b>	<b>−2.0</b>	<b>7.4</b>
			1.2	−1.1	2.3
	C45	4.0	<b>2.2</b>	<b>−1.1</b>	<b>3.3</b>
			12.5		
Panjabi et al., 1991	OC2	1.5	<b>14.1</b>		
			17.9	−18.5	36.4
			<b>21.8</b>	<b>−23.8</b>	<b>45.7</b>

The bold values are those predicted by the logarithmic flexibility function in Eq. (1), with coefficients from Table 1.

\*Range of motion.

In this study, Type III dens fractures were produced in both flexion and extension. These fractures have been attributed to a variety of mechanisms including shear, compression, flexion, extension, and combinations of all the four. Most studies have hypothesized that the mechanism of fracture is direct loading of the dens by the anterior arch of the atlas, the transverse ligament, or the lateral masses (Doherty et al., 1993; Mouradian et al., 1978; Schatzker et al., 1971). The idea that the dens may be avulsed from C2 is largely dismissed (Aymes and Anderson, 1956; Mouradian et al., 1978;

Schatzker et al., 1971). The results of this study provide some additional insights into the mechanisms of odontoid fracture, and suggest that avulsion of the odontoid due to tensile forces is a possibility. The dens is vulnerable during tensile loading because the majority of the ligaments in the O-C1-C2 ligamentous complex insert on the odontoid, or on the C2 body near the base of the odontoid. These include the apical ligament, the alar ligaments, the vertical cruciate ligament, the anterior longitudinal ligament, and the tectorial membrane. According to Myklebust et al., these ligaments combine for a total tensile strength of 1316 N (Myklebust et al., 1988). Together, they form a fibrous chord between C2 and the skull that manages approximately 75% of the tensile loads in the ligamentous upper cervical spine. All the other ligaments in the occipito-atlanto-axial complex are either small, or lax, in order to allow the remarkable mobility of the O-C1 and C1-C2 joints. The remaining major ligaments (the capsules and the ligamentum flavum) have a combined tensile strength of only 428 N.

Moments applied to the head, whether they are produced by antero-posterior or tensile forces, must be resisted by a force-couple in the upper cervical spine. During extension, the force-couple is generated by compressive stacking of the posterior elements and tension in the anterior elements, and specifically in the occipito-axial ligamentous complex. During flexion, the couple is generated by tension in the occipito-axial ligamentous complex and compression of the anterior margin of the foramen magnum and anterior arch of C1 against C2 (Fig. 4). In flexion, the moments are reacted over a much smaller distance than they are in extension, which means that for a given moment, larger ligamentous forces are generated in flexion (Fig. 4). This explains why, in our experiments, the upper cervical

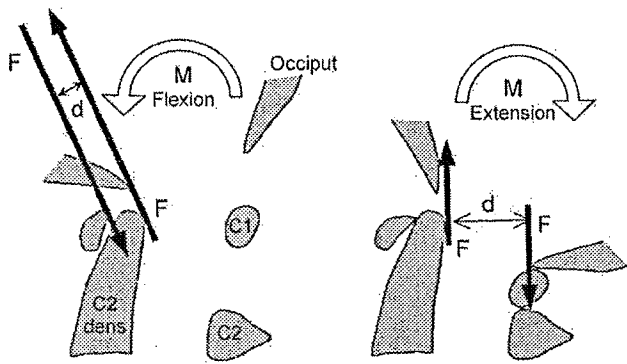


Fig. 4. Diagrams of the forces exerted during pure flexion and extension loading. The flexion moment is reacted by compression of the basion and anterior arch of C1, and by tension in the odontoid ligamentous complex. Extension is reacted by compression of the posterior elements and tension in the odontoid ligamentous complex. For a given moment, larger forces ( $F$ ) are generated in flexion than in extension because of the differences in eccentricity ( $d$ ).

spine flexion tolerance is less than the extension tolerance. It is important to note that the upper cervical spine could not be failed in pure flexion without removal of the mandible and the maxilla. This means that it is unlikely that the upper cervical spine can be injured in pure flexion without contact between the mandible and the sternum. Such a contact changes the stiffness and strength of the neck dramatically and allows it to support much larger moments by increasing the distance over which the moment is reacted (Fig. 5). This is demonstrated by tests b03f02 and b10f02, which generated large flexion moments after the anterior edge of the C2 casting cup contacted the hard palate. Based on these two tests, it appears that there may not be much difference in the flexion and extension tolerances of the ligamentous upper cervical spine when the chin-on-chest contact is taken into account.

Our results suggest that the occipito-atlantal dislocation and the atlanto-axial dislocation may occur by identical loading mechanisms that result in two different structural failures along the same load path. In the occipito-atlantal dislocation, tensile stresses cause the alar ligaments and the superior cruciform ligament to fail. This results in rapid failure of the remaining, weaker, ligaments and continued motion of the head with subsequent spinal cord and/or brain stem injury. The atlanto-axial injury may occur when the same tensile stresses cause an avulsion of the dens from the body of C2. The failed dens and the intact superior cruciform ligament cause C1 and the odontoid to separate from C2. Which of the two failures occurs is most likely related to anatomical differences and to the age of the victim (Ryan and Henderson, 1992).

One of our most interesting findings is that the upper ligamentous cervical spine is stronger in extension than

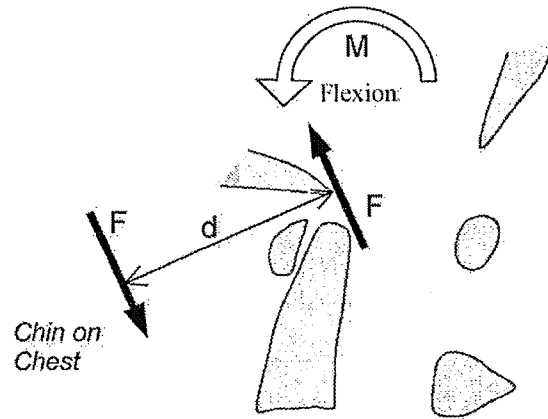


Fig. 5. Contact between the mandible and the sternum increases the eccentricity of the force-couple, which allows the reaction of much larger moments.

the lower ligamentous cervical spine, which is surprising given the epidemiology of airbag injuries and other tensile neck injuries. A recent study of neck injury tolerance in pure tension has also found the upper cervical spine to be significantly stronger (Van Ed et al., 2000). It is expected that the weakest spinal segment would be the site of injury; however, the results of the National Center for Statistics and Analysis Special Crash Investigations show a prevalence of upper cervical spine injuries in both adults and children. The discrepancy between experimental results on cadaver cervical spines and the data from automotive crashes is most likely due to the effects of the active musculature. The muscles of the cervical spine share tensile loads with the ligamentous cervical spine by providing a parallel load path. Such load sharing increases the overall strength and stability of the neck, and may provide greater protection to the caudal motion segments because of the larger size and number of muscles in the lower cervical spine (Van Ed et al., 2000).

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